

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 49 Years	3. SEX Female	3a. WEIGHT 107.90 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ CONGENITAL ANOMALY ☐ OTHER	
		Day	Month	Year			Day	Month	Year			
										PRIVACY	JAN	2024

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 stinking" belching (strong in smell, egg-like)/sulfur burps [Eructation]
 diarrhoea [Diarrhoea]
 diarrhea [Diarrhoea]
 a lot of acidity [Hyperchlorhydria]

Case Description: ***This is an auto generated narrative***

Study ID: 199-NovoDia

Study description: Trial Title: Patient support programme to support (Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEAGLUTIDE) Solution for injection (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☒ YES ☐ NO ☐ NA
15. DAILY DOSE(S) #1) 0.5 mg, qw	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous	
17. INDICATION(S) FOR USE #1) Type 2 Diabetes Mellitus (Type 2 diabetes mellitus)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA
18. THERAPY DATES(from/to) #1) DEC-2021 / Unknown	19. THERAPY DURATION #1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) LEVOTHYROXINE (LEVOTHYROXINE) ; 1998 / Ongoing #2) OMEPRAZOLE (OMEPRAZOLE) ; Ongoing #3) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METF #4) IRBESARTAN (IRBESARTAN) ; 2001 / Unknown #5) LOVASTATIN (LOVASTATIN) ; Ongoing #6) TOPIRAMATE (TOPIRAMATE) ; 2016 / Ongoing (Continued on Additional Information Page)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown to Ongoing	Type of History / Notes Current Condition duration not reported	Description Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition duration not reported	Morbid obesity (Obesity)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Novo Nordisk A/S Lise Grimmeshave Vandtaarnsvej 114 Soeborg, DK-2860 DENMARK Phone: +45 44448888		26. REMARKS Medically Confirmed: No
	24b. MFR CONTROL NO. 1169290	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 19-APR-2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:	
DATE OF THIS REPORT 10-JUN-2025	25a. REPORT TYPE ☒ INITIAL ☐ FOLLOWUP:	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

physician and their daily work to maintain an optimal diabetic control of patients through added value services such as treatment starter kit, nutrition support through NovoDia call center, individual workshops, group workshops and free A1c test.

Patient's height: 155 cm.

Patient's weight: 107.9 kg.

Patient's BMI: 44.91155050.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping)" beginning on JAN-2024 , "diarrhoea(Diarrhoea)" beginning on MAR-2024 , "diarrhea(Diarrhea)" with an unspecified onset date , "a lot of acidity(Hyperacidity)" with an unspecified onset date and concerned a 49 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from DEC-2021 and ongoing for "Type 2 Diabetes Mellitus",

Dosage Regimens:

Ozempic 0.25/0.50 mg: ??-DEC-2021 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes mellitus, Morbid obesity, High cholesterol, Gastritis, Hypothyroidism, Arterial hypertension
Procedure: Intragastric balloon.

Concomitant medications included - LEVOTHYROXINE, OMEPRAZOLE, XIGDUO(DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE), IRBESARTAN, LOVASTATIN, TOPIRAMATE.

Batch Numbers:

Ozempic 0.25/0.50 mg: ASKU, ASKU;

Action taken to Ozempic 0.25/0.50 mg was reported as Dose Decreased.

The outcome for the event "stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping)" was Recovering/resolving.

On MAR-2024 the outcome for the event "diarrhoea(Diarrhoea)" was Recovered.

The outcome for the event "diarrhea(Diarrhea)" was Unknown.

The outcome for the event "a lot of acidity(Hyperacidity)" was Unknown.

Reporter's causality (Ozempic 0.25/0.50 mg) -

stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping) : Possible

diarrhoea(Diarrhoea) : Possible

diarrhea(Diarrhea) : Unknown

a lot of acidity(Hyperacidity) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -

stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping) : Possible

diarrhoea(Diarrhoea) : Possible

diarrhea(Diarrhea) : Possible

a lot of acidity(Hyperacidity) : Unlikely

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE) Solution for injection; Regimen #2	0.25 mg, qw; Subcutaneous	Type 2 Diabetes Mellitus (Type 2 diabetes mellitus)	Ongoing; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#3) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE) ; 2018 / Ongoing

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition duration not reported	High cholesterol (Blood cholesterol increased);
Unknown to Ongoing	Current Condition duration not reported	Gastritis (Gastritis);
Unknown to Ongoing	Current Condition duration not reported	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition duration not reported	Arterial hypertension (Hypertension);
Unknown	Procedure	Bariatric gastric balloon insertion (Bariatric gastric balloon insertion);